



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,518	05/25/2000	LYLE ARMSTRONG	106141	2222

25944 7590 04/23/2002

OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER

CHAUDHRY, MAHREEN F

ART UNIT PAPER NUMBER

1627

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/530,518

Applicant(s)

ARMSTRONG ET AL.

Examiner

Mahreen Chaudhry

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Acknowledgement is made of the amendment filed February 8, 2002. Claims 22, 28, 30, 39 and 40 are amended. Claims 43-47 have been added.

Claim Objections

2. Claim 47 is objected to because of the following informalities: in line 9 of the claim "hydrophobic medium" may need to be replaced with "hydrophilic medium." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 22-47, the phrase "X represents a group which limits the diffusion of the α -keto acid produced by the deamination of the cyclic amino acid" is vague and indefinite. The chemical group "X" is claimed functionally without recitation of any specific chemical structure and the meaning of the term "X" is indefinite in that it does not specifically point out what chemical groups are encompassed by the invention. The specific chemical group to which

this claim is directed to is unclear from a mere recitation of a characteristic; in the instant case, the specific chemical substitutions to which "X" refers is unclear from the description that they limit the diffusion of the α -keto acid produced by the deamination of the cyclic amino acid.

Applicant argues that one of ordinary skill would understand what chemical groups can be substituted on cyclic amino acid radical. Applicant additionally argues that the specification provides examples of such chemical groups, but that these chemical groups do not limit the scope of the claims. Applicant further argues that the specification discloses a method for determining whether or not a "potential X chemical group limits the diffusion of α -keto acid."

It is the examiner's position that although one having ordinary skill in the art would be able to envision an infinite number of chemical groups that could be substituted on a cyclic amino acid, those specific chemical groups that would limit the diffusion of the α -keto acid would not be clear. It is considered that a recitation of the chemical group "X" in terms of its function of limiting the diffusion of α -keto acids does not particularly point out the invention because it would not be clear to one having ordinary skill what specific chemical groups "X" refers to or what specific chemical compounds could be utilized according to the instant invention. It is considered that one having ordinary skill in the art would not be able to discern the metes and bounds of the claimed invention by the recited functional limitation. Specifically one having ordinary skill would not be able to readily discern which specific chemical group substitutions on a cyclic amino acid would result in limited diffusion of the α -keto acid produced by the deamination of the cyclic amino acid.

Applicant contends that the specification provides a method for determining whether or not an X chemical group substitution results in a compound which is able to limit the diffusion of

Art Unit: 1627

an α -keto acid and that such compounds could then be used according to the instant method. However, the presence of a recitation, in the specification, of a method for determining which X chemical group substitutions would result in a compound that limits the diffusion of alpha keto acids neither particularly points out nor distinctly claims which specific substitutions limit the diffusion of α -keto acids. One having ordinary skill in the art would not be able to understand which specific chemical substitutions the X substitution refers to and which specific chemical compounds the instant claims are directed to. Without a recitation of specific chemical groups or specific classes of chemical groups in the claim, the phrase "X represents a group which limits the diffusion in the culture medium of the a-keto acid produced by the deamination of the cyclic amino acid" is indefinite.

6. Regarding claims 23 and 31, the limitation, "X is chosen from hydrophobic groups" and regarding claim 47, the limitation, "X represents any group of the hydrophobic type which limits the diffusion of the a-keto acid" is unclear. The terms "hydrophobic groups" and "any group of the hydrophobic type" are considered to be unduly broad and encompass more than the specification could possibly support.

Applicant argues that one having ordinary skill would understand that hydrophobic groups are non-polar and are insoluble in water. It is the examiner's position, that although the meaning of the term "hydrophobic group" would be apparent to one having ordinary skill in the art, the specific hydrophobic chemical groups that would be appropriate substitutions for the cyclic amino acid and that would result in limited diffusion of an α -keto acid is not clear.

Hydrophobic groups include a vast range of chemical groups and the specific chemical groups

which would be substituted on the amino acid to result in limited diffusion of an α -keto acid formed by the deamination of the cyclic amino acid would not be readily understood by one having ordinary skill in the art.

7. Regarding claim 43, the limitation “X represents a group that associates with or binds to constituents of the cells of the microorganism to limit diffusion” is vague and indefinite. The chemical group “X” is claimed functionally without recitation of any specific chemical structure and the meaning of the term “X” is indefinite in that it does not specifically point out what chemical groups are encompassed by the invention. The specific chemical group to which this claim is directed to is unclear from a mere recitation a characteristic; in the instant case, the specific chemical substitutions to which “X” refers is unclear from the description that they associate with or bind to constituents of the cell of the microorganism to limit diffusion. One having ordinary skill in the art would not be able to determine the metes and bounds of the claimed invention since one of ordinary skill would not understand which specific chemical groups would bind to a cell constituent to ultimately limit diffusion. Without specifically setting forth the chemical groups, the class of chemical groups or chemical structures, the claim is considered indefinite.

8. Regarding claim 44, the limitation “X represents a group that limits diffusion in hydrophilic medium” is vague and indefinite. The chemical group “X” is claimed functionally without recitation of any specific chemical structure and the meaning of the term “X” is indefinite in that it does not specifically point out what chemical groups are encompassed by the

Art Unit: 1627

invention. The specific chemical group to which this claim is directed to is unclear from a mere recitation a characteristic; in the instant case, the specific chemical substitutions to which "X" refers is unclear from the description that they limit diffusion in hydrophilic medium. One having ordinary skill in the art would not be able to determine the metes and bounds of the claimed invention since one of ordinary skill would not understand which specific chemical groups would limit diffusion in hydrophilic medium. Without specifically setting forth the chemical groups, the class of chemical groups or chemical structures, the claim is considered indefinite.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 30, 31 and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by each of U.S. Patent 4,937,352 issued to Voelter, U.S. Patent 4,507,230 issued to Tam et al., U.S. Patent 5,668,254 issued to Deghengi and U.S. Patent 5,173,434 issued to Morris et al. Voelter discloses histidine derivatives including 3-propylhistidine, 3-isopropylhistidine, 3-butylhistidine, 3-cyclopropylhistidine, 3-cyclopentylhistidine and 3-benzylhistidine which are all encompassed by the general formula recited in the claims (Column 11, Lines 25-33). Tam et al. disclose the compound 3-benzyltyrosine which is also included by the general formula recited in the claims (Column 11, Line 3). Deghengi discloses 2-methyl tryptophan which is also included by general

Art Unit: 1627

formula I (Column 4, Lines 37-41). In addition, Morris et al. disclose p-nitrophenylalanine which is also encompassed by formula recited in claims 30-31.

Applicant argues that the instant method is distinguished from the above cited references in that none of the references teach a compound in which the cyclic amino acid is substituted with two or three chemical groups. However, it is the examiner's position that the term "X" reads on hydrogen substitutions as well as non-hydrogen substitutions. Therefore the cited chemical compounds anticipate the claims as written.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 22-23, 25-29, 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,173,434 issued to Morris et al. in view of U.S. Patent 3,725,203 issued to Sellers. Morris et al. disclose a method for the identification of Proteus bacteria by the ability of these bacteria to deaminate L-amino acids to α -keto acids (Column 13, Lines 1-20). Morris et al. teach that the amino acid derivative p-nitrophenylalanine is utilized as the substrate to produce p-nitrophenylpyruvic acid which is detected by the appearance of brown color after the addition of NaOH (Column 13, Lines 11-15). Morris et al. teaches that an inoculum containing a bacterial isolate is added to a medium containing dimethyl coumarin and p-nitrophenylalanine (Column 13, Lines 22-40).

Art Unit: 1627

Morris et al. do not expressly disclose that the amino acid detecting agent is present in a culture medium. However, the identification of proteus bacteria by the addition of amino acid detecting agents to culture media is well-known. Sellers discloses that utilization of phenylalanine or tryptophan in culture permits identification of proteus bacteria by the production of α -keto acid by deaminase activity (Column 3, Lines 13-18). Sellers teaches that the bacteria are incubated with phenylalanine and then treated with ferric chloride which reacts with phenylpyruvic acid to produce a green color (Column 3, Lines 13-18). Sellers discloses a culture medium containing L-tryptophan, L-phenylalanine, ferric ammonium citrate, brom cresol purple, brom thymol blue and agar (Column 3, Lines 41-50). Sellers teaches that L-tryptophan may be added in an amount sufficient to produce a detectable reaction, specifically in an amount between 1 and 5 g/l (Column 4, Lines 6-18).

Since bacterial deaminase activity results in the production of a detectable α -keto acid from both L-phenylalanine and the L-phenylalanine derivative, p-nitrophenylalanine, it would have been obvious to one having ordinary skill in the art to have substituted the L-phenylalanine in the culture medium taught by Sellers for the L-phenylalanine derivative, p-nitrophenylalanine, taught by Morris et al. It would additionally have been obvious that any amino acid or amino acid derivative capable of producing an α -keto acid could be utilized in a culture media for the detection of bacteria having deaminase activity since methods of detecting such α -keto acids are known in the art. Furthermore, it would have been obvious to have prepared these amino acid derivatives using methods known in the art. The point of novelty in the instant invention may be the substitution of the amino acid with a chemical group which limits the diffusion of the resulting α -keto acid in hydrophilic media thus permitting detection of a distinct colored product

Art Unit: 1627

which does not diffuse through the media. However, the claims do not expressly recite what chemical groups limit the diffusion of the α -keto acid, how such diffusion is limited and the how such diffusion permits improved assay of deaminase activity.

Applicant argues that neither Morris et al. nor Seller et al. teach a compound in which a cyclic amino acid is substituted with 2 to 3 "X" groups. Applicant further argues that Morris et al. teaches away from the instant invention since Morris et al. teaches an amino acid substituted with a NO_2 group which would promote diffusion of the α -keto acid.

As discussed above, it is the examiner's position that as written, the group "X" reads on any hydrogen and non-hydrogen substitution. With regard to applicant's assertion that Morris et al. teach away from the instant invention by utilizing an NO_2 substituted amino acid since such an amino acid would promote diffusion of the α -keto acid, it is considered that since the claims do not set forth specific chemical groups to which "X" refers, but rather claim "X" in vague functional terms, "X" would read on any chemical group. Applicant merely asserts that NO_2 substituted amino acid would promote diffusion but has provided no specific evidence to support this assertion. It is the examiner's position that since the invention has not been specifically set forth in the claims such that one of ordinary skill in the art would understand the metes and bounds of the invention, applicant's allegation that the NO_2 substituted amino acid is excluded by the claimed subject matter is not persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1627

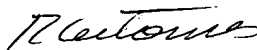
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc
April 18, 2002


RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200